

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY	)
AVERAGE WHOLESALE PRICE	) MDL NO. 1456
LITIGATION	) Civil Action No. 01-12257-PBS
	) Subcategory Case No: 03-10643-PBS
THIS DOCUMENT RELATES TO:	)
<i>The City of New York, et al.</i>	) Judge Patti B. Saris
v.	)
<i>Abbott Laboratories, et al.</i>	)
	)

**PLAINTIFFS' REPLY LOCAL RULE 56.1 STATEMENT OF UNDISPUTED  
MATERIAL FACTS AS TO PUREPAC PHARMACEUTICAL CO.**

Pursuant to Rule 56.1 of the Local Rules of this Court, plaintiffs hereby submit this Reply Statement of Undisputed Material Facts Applicable to Purepac Pharmaceutical Co. ("Purepac") in support of their Motion for Partial Summary Judgment.

**I. PUREPAC SPECIFIC FACTS**

**1. The Purepac Drugs and NDCs that have been examined in connection with this motion are set forth in Exhibit A hereto. This exhibit also sets forth Purepac's Published AWP's and WACs for these Drugs and NDCs, any operative Federal Upper Limit ("FUL") and Purepac's AMPs. The exhibit also notes which NDCs are associated with package sizes that set the FUL.**

**PUREPAC'S RESPONSE: Purepac does not dispute that Plaintiffs' Exhibit A purports to contain AWP's and WACs and any operative FUL for Purepac Drugs. However, Purepac disputes the data set forth in Exhibit A to the extent they are not properly supported by cited evidence in the record.**

**Plaintiffs' Reply to Statement #1:** Purepac's dispute as to the data in Exhibit A not being properly supported by evidence in the record is baseless. Plaintiffs properly cited Purepac as the source of the AMP data and the First Databank NDDF data file (Alabama Production, FDB-AWP 030785-030795) as the source of all other data. See Exhibit A at p.9 to Plaintiffs'

Local Rule 56.1 Statement of Undisputed Material Facts as to Purepac Pharmaceutical Co. (“Purepac 56.1 Statement”) [Docket No. 6068, Sub-docket No. 69]. This is the same source cited by Purepac’s expert Dr. Addanki. *See* Affidavit of Dr. Sumanth Addanki dated May 15, 2009 [Docket No. 6056] at Exhibit 2 (identifying “First DataBank (Alabama Production) Data and NDDF (National Drug Data File)<sup>TM</sup> Documentation Manual (Rev. April 2000)” as a Data source).

The AMP data was authenticated at the June 20, 2008 Rule 30(b)(6) Deposition of Purepac. *See* Purepac 30(b)(6) (O’Malley, Patricia) dated 6/20/08 (“Purepac 30(b)(6)(O’Malley) 6/20/08 Dep.”) (Reply Exhibit A attached hereto) at 227:5-229:4.

*See also* Reply Affidavit of Joanne M. Cicala, sworn to June 30, 2009 and submitted in further support of plaintiffs’ motion for partial summary judgment at ¶2, which is incorporated herein.

**2. The specific Purepac Drugs at issue are the Clonazepam .5 MG Tablet, Enalapril Maleate 20 MG Tablet, Isosorbide Mononitrate 60 MG Tablet and Lorazepam 1 MG Tablet.**

**PUREPAC’S RESPONSE:** Purepac does not dispute that the four drugs identified are the designated FUL fraud drugs pursuant to CMO 33, September 14, 2007.

**Plaintiffs’ Reply to Statement # 2:** No reply is required.

**3. Purepac has executed the federal Medicaid rebate agreement. *See* Answer and Affirmative Defenses of Purepac Pharmaceutical Co. to Revised First Amended Consolidated Complaint [Docket # 4818] (“Purepac Answer”) at ¶132; *see also* *Commonwealth of Mass. v. Mylan Labs.*, 2008 WL 5650859 \*25 (D. Mass. Dec. 23, 2008) (“Mylan”). Purepac signed the federal Medicaid rebate agreement because Purepac wanted its products to be reimbursed by Medicaid. *See* Purepac 30(b)(6) (O’Malley, Patricia) dated 6/20/08 (“Purepac 30(b)(6)(O’Malley) 6/20/08 Dep.”) (Exhibit B) at 125:5-18.**

**PUREPAC’S RESPONSE:** Purepac does not dispute paragraph 3, except that Purepac signed the Agreement because federal law mandates that Purepac sign the agreement in order for its customers to seek and obtain reimbursement from Medicaid for their sales of Purepac products.

**Plaintiffs' Reply to Statement # 3:** The parties agree that Purepac signed the federal Medicaid rebate agreement in order for its customers to seek and obtain reimbursement from Medicaid. No further reply is required.

**4.** Purepac was required as a matter of law to familiarize itself with the legal requirements, standards and procedures of the Medicaid reimbursement formulas, including those of the New York State Medicaid program. *Mylan*, 2008 WL 5650859 at \*25.

**PUREPAC'S RESPONSE:** Purepac disputes the statement of paragraph 4 because it is not a proper statement of fact for a Rule 56.1 statement, but is instead a question of law. In fact, Purepac's obligations under the Rebate Agreement are limited to compliance "with the conditions of 42 U.S.C. section 1396s, changes thereto and implementing regulations as the Secretary deems necessary and specifies by actual prior notice to the manufacturer." See sample agreement available at <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf>. Purepac further disputes that Mylan has any legal effect in this case, as it involved different issues and is a nonfinal decision denying the parties' motions for summary judgment. See *Gonzalez v. Rodriguez*, 407 F.3d 425 (1st Cir. 2005) (collateral estoppel requires, among other conditions, identity of issues, and finality of the judgment).

**Plaintiffs' Reply to Statement # 4:** It is indisputable that Judge Saris ruled in *Mylan* that, at a minimum, the defendants in that case were required to familiarize themselves with the legal requirements, standards and procedures of the Medicaid program. *Commonwealth of Mass. v. Mylan Labs.*, 608 F.Supp.2d 127, 154 (D. Mass. Dec. 23, 2008) ("*Mylan*"). The Court wrote that this requirement included the "procedures and legal requirements applicable to reimbursement." *Id.* The remainder of Purepac's response is disputed and irrelevant. No further reply is required.

**5.** Purepac knew that its published prices were used for Medicaid reimbursement. *Mylan*, 2008 WL 5650859 at \* 16.

**PUREPAC'S RESPONSE:** Purepac disputes the statement that it knew that its suggested published prices were used for Medicaid reimbursement because the term "published prices" is unduly vague and ambiguous. Moreover, the citation does not set forth the facts that it purports to support. In fact, Purepac's (30)(b)(6) deponent

**Patricia O'Malley testified that she did not know that WAC was used for Medicaid reimbursement. Purepac 30(b)(6)(O'Malley) 9/19/07 Dep. at 91:13-15.**

**Plaintiffs' Reply to Statement # 5:** Purepac's Corporate Designee testified that Purepac understood its published AWP's were used for Medicaid reimbursement. The testimony follows:

"A: One of the questions, the answers I gave you before had to do with the AWP, was it our understanding it was used for reimbursement, and I believe that I said that it was our understanding it was used for Medicaid reimbursement. It was our understanding it was also used for other third-party payer for reimbursement programs."

Purepac 30(b)(6)(O'Malley, Patricia) dated 6/20/2008 ("Purepac 30(b)(6) O'Malley) 6/20/2008 Dep.") (Exhibit B to Purepac 56.1 Statement [Dkt. No. 6068, Sub-dkt. No. 69]) at 67:5-11.

Purepac's dispute is frivolous. Under the federal Medicaid rebate agreement, Purepac had an obligation and a duty to understand Medicaid reimbursement.

**6. Purepac knows that third party payor reimbursement can be based on AWP's. See Deposition of Roberto Miranda dated 10/19/2007 ("Miranda Dep. 10/19/07") (Exhibit C) 79:20-80:1. It was important that the information printed in the pricing compendium be accurate because third party payors used the information as the basis for reimbursement. See Deposition of Bradford Cunningham dated 10/23/2007 ("Cunningham Dep. 10/23/07") (Exhibit D) at 107:15-22.**

**PUREPAC'S RESPONSE:** Purepac disputes the statements in paragraph 6 to the extent that they are purportedly based on what Purepac now knows when neither of the cited deponents testified to what Purepac now knows and there is not allegation as to what Purepac knew at any point during the relevant time period. Purepac further disputes the use of the term "accurate" because it is unduly vague and ambiguous. Purepac further disputes this statement because Plaintiffs noticed and took the deposition of Purepac's 30(b)(6) designee in this case and did not ask any questions regarding this issue. Purepac does not dispute that in his deposition Mr. Cunningham stated that Purepac wanted "to make sure that First DataBank got notice [of changes in AWP and WAC] . . . because the information was used by so many third-party payors for reimbursement" but disputes the remainder of paragraph 6.

**Plaintiffs' Reply to Statement # 6:** Purepac's Corporate Representative testified:

"A: One of the questions, the answers I gave you before had to do with the AWP, was it our understanding it was used for reimbursement, and I believe that I said that it was our understanding it was used for Medicaid reimbursement. It was our understanding it was also used for other third-party payer for reimbursement programs."

Purepac 30(b)(6)(O'Malley, Patricia) dated 6/20/2008 ("Purepac 30(b)(6) O'Malley) 6/20/2008 Dep.") (Exhibit B to Purepac 56.1 Statement [Dkt. No. 6068, Sub-dkt. No. 69]) at 67:5-11. Thus, Purepac's dispute of the Statement that it knew third party payor reimbursement can be based on AWP's is baseless.

Nor can Purepac dispute that it ensured the accuracy of its published prices in the compendia. Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B to Purepac 56.1 Statement [Dkt. No. 6068, Sub-dkt. No. 69]) at 42:16-43:5, quoted as follows:

Q: Purepac would either verify the prices that they received back from the publisher or they would suggest changes to the documents, the prices that they received from the publisher.

A: Well, I believe what I said was that when Purepac would receive the request, there was someone at Purepac within sales and marketing group who would, in fact, confirm that the prices were, in fact, our published WAC and AWP at the time. Or I believe they would, if it wasn't correct in the compendia, the change, the correction would be made, not a suggestion."

Further responding, it cannot reasonably be disputed that Mr. Miranda's testimony covers at least the majority of the time period at-issue (1997 to 2003). Mr. Miranda has worked in bids and contracts at Purepac since 1984 first as bids and contracts administrator (1984-1989), then as manager (1989-2000 or 2001) and since 2000 or 2002 as contract manager of key accounts. *See* Deposition of Roberto Miranda dated 10/19/2007 ("Miranda Dep. 10/19/07") (Reply Exhibit B attached hereto) at 14:2-15:10. Mr. Cunningham's testimony is relevant to the time period at issue. Mr. Cunningham served as vice president of sales and marketing from 2000 to 2002. *See* Deposition of Bradford Cunningham dated 10/23/2007 ("Cunningham Dep. 10/23/07") (Reply Exhibit C attached hereto) at 23:6-24:5.

#### **Purepac Set and Reported Its AWP's and WAC's**

**7. At all times, from 1997 to 2005, Purepac reported or caused to be reported the AWP's (as suggested AWP's) for its drugs to the publishing compendia. *See* Purepac**

30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B) at 36:19-38:16; 60:3-61:10; 62:19-63:1; Purepac 30(b)(6)(O'Malley, Patricia) dated 9/19/07 ("Purepac 30(b)(6)(O'Malley) 9/19/07 Dep.") (Exhibit E) at 81:7-17; The Alharma Defendants' Supplemental Responses and Objections to Plaintiff's First Set of Interrogatories and Request for Production to Defendants, *State of Alabama v. Abbott Laboratories, Inc., et al.*, CV 2005-21, Cir. Court of Montgomery County, Alabama, June 20, 2006, p. 12, response to Interrogatory No. 11 ("Alharma Supp. Resp. to Alabama's First Set of Interrogatories") (Exhibit F); *Mylan*, 2008 WL 5650859 at \*10.

**PUREPAC'S RESPONSE:** Purepac does not dispute the statements set forth in paragraph 7.

**Plaintiffs' Reply to Statement # 7:** No further reply is required.

8. Purepac reported or caused to be reported the same AWP to all three of the national compendia. See Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B) at 122:10-21.

**PUREPAC'S RESPONSE:** Purepac does not dispute the statement set forth in paragraph 8.

**Plaintiffs' Reply to Statement # 8:** No further reply is required.

9. Purepac had only one AWP in place at any given time. See Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B) at 122:10-21.

**PUREPAC'S RESPONSE:** Purepac does not dispute the statement set forth in this paragraph, to the extent that it refers to a specific NDC code.

**Plaintiffs' Reply to Statement # 9:** No further reply is necessary.

10. At all times, from 1997 to 2005, Purepac reported or caused to be reported WACs for its drugs to the publishing compendia. See Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B) at 61:17-66:15; *Mylan*, 2008 WL 5650859 at \*10.

**PUREPAC'S RESPONSE:** Purepac does not dispute the statement set forth in this paragraph.

**Plaintiffs' Reply to Statement # 10:** No further reply is required.

11. Purepac reported or caused to be reported the same WACs to all three of the national compendia. See Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B) at 122:22-123:4; Alharma Supp. Resp. to Alabama's First Set of Interrogatories, response to Interr. No. 11 (Exhibit F).

**PUREPAC'S RESPONSE:** The citation to the 30(b)(6) deposition does not support the statement in paragraph 11. Nevertheless, Purepac does not dispute the statement set forth in paragraph 11.

**Plaintiffs' Reply to Statement # 11:** No further reply is required.

12. Purepac knew and controlled the WACs for its drugs that were being published by the national drug pricing compendia. *See* Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B) at 65:14-66:15 (Purepac supplied the WACs that appeared in the compendia). Purepac had only one WAC at any given time. *See* O'Malley (6/20/08) 30(b)(6) Dep. (Exhibit B) at 122:22-123:4.

**PUREPAC'S RESPONSE:** Disputed to the extent that this "fact" is unduly vague in terms of the time period to which it allegedly pertains. Although Purepac does not dispute that it supplied WACs for its drugs to all three national pricing compendia, it denies the remainder of this paragraph; the cited parts of the record do not support that Purepac "controlled" the WACs.

**Plaintiffs' Reply to Statement # 12:** The parties agree that Purepac supplied the WACs to the publishing compendia. Purepac cannot reasonably dispute the remainder of the Statement. The cited 30(b)(6) testimony supports the statement.

"Q:...If a WAC appears in the publishing compendia for a Purepac drug, is it fair to say that that WAC was supplied to the compendia by Purepac?

Mr. Fleder: Same objection.

A: As I recall, I believe that it would have been supplied by –

Q: Okay.

A: -- Purepac."

Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B to Purepac 56.1 Statement [Dkt. No. 6068, Sub-dkt. No. 69]) at 65:14-66:15. And,

"Q: Same thing for WAC, there would only be one WAC in place at any given time for the same four drugs?

A: I believe that would also be the case, yes."

O'Malley (6/20/08) 30(b)(6) Dep. (Exhibit B to Purepac 56.1 Statement [Dkt. No. 6068, Sub-dkt. No. 69]) at 122:22-123:4.



Moreover, Purepac admits in its response to Statement 14 that Purepac's understanding was that the pricing compendia would publish the WACs and suggested AWP's that Purepac submitted as Purepac's WACs and AWP's.

**13. Purepac knew and controlled the published prices for its drugs that appeared in the national drug pricing compendia. Purepac received price verifications from Red Book. See Purepac 30(b)(6)(O'Malley) 9/19/07 Dep. (Exhibit E) at 214:9-215:4; Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B) at 39:11-43:14. Purepac would confirm the prices were Purepac's published AWP's and WACs. See *Id.* If the prices were not correct, Purepac would make a correction. See *Id.***

**PUREPAC'S RESPONSE: Disputed to the extent that this "fact" is unduly vague in terms of the time period to which it allegedly pertains. However, Purepac did at certain times supply suggested AWP's and WACs to the national drug pricing compendia. In addition, the cited parts of the record do not support Plaintiffs' assertion that Purepac did "control[] the published prices for its drug."**

**Plaintiffs' Reply to Statement # 13:** The parties agree that Purepac supplied suggested AWP's and WACs to the publishing compendia. Responding further, Purepac admits in its response to Statement 14 that the pricing compendia published the WACs and suggested AWP's that Purepac submitted as Purepac's WACs and AWP's.

Beyond that, Purepac disputes the above Statement only to the extent it does "not support the [p]laintiffs' assertion that Purepac did 'control[] the published prices for its drug.'" This means that Purepac does not dispute that "Purepac would confirm the prices were Purepac's published AWP's and WACs," or that "[i]f the prices were not correct, Purepac would make a correction." Purepac's 30(b)(6) testimony speaks for itself:

"Q: Do you have any recollection of any of the price reporting services ever sending Purepac a document showing what their then current information was for Purepac and asking Purepac to verify or confirm to them that the information was correct?

A: I believe – I recall also in discussion yesterday in prepping that Red Book sends out an annual – annually, I believe – list of products to confirm, requesting that the manufacturer, Purepac in this case, confirm that the products listed with other pertinent information was correct.

Q: And –

A: And current.



Q: And was it Purepac's practice to comply with this request from Red Book to check the numbers, make sure they were right, and send back the confirmation.

A: I believe that would be a reason, yes."

Purepac 30(b)(6)(O'Malley) 9/19/07 Dep. (Exhibit B to Purepac 56.1 Statement [Dkt. No. 6068, Sub-dkt. No. 69]) at 214:9-215:4;

"Q: Purepac would either verify the prices that they received back from the publisher or they would suggest changes to the documents, the prices that they received from the publisher.

A: Well, I believe what I said was that when Purepac would receive the request, there was someone at Purepac within the sales and marketing group who would, in fact, confirm that the prices were, in fact, our published WAC and AWP at the time. Or I believe they would, if it wasn't correct in the compendia, the change, the correction would be made, not a suggestion."

Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B to Purepac 56.1 Statement [Dkt. No. 6068, Sub-dkt. No. 69]) at 42:16-43:5.

**14. When Purepac sent WACs and AWP's to the drug pricing compendia, it was Purepac's understanding that the pricing compendia were going to publish them as Purepac's WACs and AWP's. See Purepac 30(b)(6)(O'Malley) 9/19/07 Dep. (Exhibit E) at 132:20-133:5; Purepac 30(b)(6) (O'Malley) 6/20/08 Dep. (Exhibit B) at 65:14-66:15.**

**PUREPAC'S RESPONSE:** Disputed to the extent that this "fact" is unduly vague in terms of the time period to which it allegedly pertains. However, Purepac does not dispute that, at certain times, "it was Purepac's understanding that the pricing compendia [would] publish [the WACs and suggested AWP's that Purepac submitted] as Purepac's WACs and AWP's."

**Plaintiffs' Reply to Statement #14:** The parties agree that it was Purepac's understanding that the pricing compendia would publish, at certain times at a minimum, the WACs and suggested AWP's that Purepac submitted as Purepac's WACs and AWP's. Purepac cannot reasonably dispute that it had this understanding throughout the 1997-2005 period. Purepac's Corporate Representative's June 20, 2008 testimony covered the 1997 to 2005 time period. See Purepac 30(b)(6) (O'Malley) 6/20/08 Dep. (Reply Exhibit A attached hereto) at 32:9-

13. Responding further, it cannot reasonably be disputed that plaintiffs have an evidentiary basis for the 1997 to 2005 time period given that Ms. O'Malley was designated by Purepac as its Rule 30(b)(6) witness for the entire period at issue and Ms. O'Malley understood that her testimony covered that period. *See Id.*

**Purepac's Published AWP's and WACs had No Relationship to Actual Prices**

15. At launch, for each of its generic drugs, Purepac generally set the AWP around 10% below the corresponding brand AWP. *See O'Malley, Patricia (6/20/08) 58:13-17; O'Malley (9/19/2007) 30(b)(6) Dep. (Exhibit E) at 83:20-84:7.*

**PUREPAC'S RESPONSE:** To the extent that Plaintiffs state that Purepac suggested an AWP at around 10.1% below the corresponding brand AWP, Purepac does not dispute this paragraph.

**Plaintiffs' Reply to Statement # 15:** The parties agree that Purepac generally set its AWP around 10.1% below the corresponding brand AWP. No further reply is required.

16. Purepac's AWP's were not true prices. *Mylan, 2008 WL 5650859 at \* 18.*

**PUREPAC'S RESPONSE:** Disputed to the extent that this statement is unduly vague in terms of the time period to which it allegedly pertains. Moreover, paragraph 16 purports to state a legal conclusion not a fact. In addition, Purepac also disputes that Mylan has any legal effect in this case, as it involved different issues and is a nonfinal decision denying the parties' motions for summary judgment. *See Gonzalez v. Rodriguez, 407 F.3d 425 (1st Cir. 2005) (collateral estoppel requires, among other conditions, identity of issues, and finality of the judgment).* Purepac further disputes this statement because the phrase "true prices" is unduly vague and ambiguous.

**Plaintiffs' Reply to Statement # 16:** The Court has defined AWP as "the average price which wholesalers sell drugs to their customers, including physicians and pharmacies." *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F.Supp.2d 20, 94 (D.Mass. June 21, 2007). In the class trial the Court determined that defendants' AWP's were false and misleading when they did not represent true average wholesale prices that "approximated provider actual acquisition costs or [were] within well-established industry expectations..." *Id.*

at 95. Purepac cannot reasonably dispute that its AWP's are not "the average price(s) which wholesalers sell drugs to their customers" or that they "approximated provider actual acquisition costs or [were] within well-established industry expectations." Purepac has put nothing in record to demonstrate veracity of its AWP's. Given this and Purepac's testimony regarding how AWP's were set (*see* Statement #15), Purepac cannot reasonably dispute that its AWP's did not reflect true (or actual) prices to Purepac customers.

**17. Purepac does not sell any of its generic drugs at AWP. *See* Purepac 30(b)(6)(O'Malley) 9/19/07 Dep. (Exhibit E) at 88:1-6.**

**PUREPAC'S RESPONSE:** Disputed as written. What Purepac currently does is not relevant. Moreover, the testimony does not relate to the present. Purepac does not dispute the statement in paragraph 17 to the extent it concerns the four generic drugs at issue at some undefined time. To the extent the statement concerns any of Purepac's other products, the statement is not relevant to this motion.

**Plaintiffs' Reply to Statement # 17:** The parties agree that Purepac did not sell the four generic drugs at AWP at some time. Responding further, Ms. O'Malley's testimony in *Massachusetts v. Mylan et al.* (CA. No. 03-11865 PBS) covered the 1997 to 2003- time period. *See* Purepac 30(b)(6)(O'Malley) 9/19/07 Dep. (Reply Exhibit D attached hereto) at 37:3-8. Ms. O'Malley clearly testified as follows: "Q: Did Purepac sell any product at the AWP price? A: The question being did Purepac sell product to a direct customer at the AWP – Q: Any customer. Direct, indirect, anybody. A: No. I do not believe so." Purepac 30(b)(6)(O'Malley) 9/19/07 Dep. (Exhibit E to Purepac 56.1 Statement [Dkt. No. 6068, Sub-dkt. No. 69]).

**18. Purepac's definition of AWP is different than FDB's definition of AWP. Purepac did not have an understanding that AWP represents the average wholesale price a wholesaler would charge for a particular product. *See* Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B) at 214:5-216:14.**

**PUREPAC'S RESPONSE:** Disputed to the extent that the second "fact" is unduly vague in terms of the time period to which it allegedly pertains. Otherwise, Purepac does not dispute the statements in paragraph 18.

**Plaintiffs' Reply to Statement # 18:** No further reply is required.

19. Typically, the published Purepac AWP is higher than the published WAC. *See* Cunningham Dep. 10/23/07 (Exhibit D) at 195:21-196:9. And typically, the published WAC is higher than contract prices. *See Id.* Purepac established WACs at a discount off AWP. *See* Purepac 30(b)(6)(O'Malley) 9/19/07 Dep. (Exhibit E) at 100:12-19.

**PUREPAC'S RESPONSE:** Disputed. Mr. Cunningham's statements are not admissions of the company. Plaintiffs had the opportunity to depose Purepac's 30(b)(6) witness, Patricia O'Malley and did not ask any questions that could have established these facts as undisputed facts attributable to Purepac. Purepac also disputes these "facts" to the extent they relate to the present and therefore are not relevant and not supported by the record. Purepac disputes the last sentence of paragraph 19 to the extent that it is controverted by Purepac's statement that AWP, WAC and contract price moved independently. *See* Plaintiffs' Exhibit E at 128:19-129:7; 145:18-147:11; see also paragraph 21, *infra*.

**Plaintiffs' Reply to Statement # 19:** Purepac disputes the statement only to the extent it is not based on testimony from a 30(b)(6) witness. Purepac's 30(b)(6) designee, Ms. O'Malley, clearly testified that the initial WAC prices at launch were "set lower than the suggested AWP price." Purepac 30(b)(6)(O'Malley) 9/19/07 Dep. (Reply Exhibit D attached hereto) at 70:15-21, quoted as follows:

Q: How did Purepac set WACs that it reported to the publishing compendia?

A: Best I can recall, the WAC prices, certainly the initial WAC price, would be set at the time a product was launched. And it was, again, the best I can recall, set lower than the suggested AWP price."

And Purepac's Corporate designee testified that contract prices were typically less than WAC. Purepac 30(b)(6)(O'Malley) 9/19/07 Dep. (Reply Exhibit D attached hereto) 90:9-13.

"Q: And these contract prices typically would be lower than the WAC that Purepac reported; isn't that right?

A: The contract prices would typically, my recollection, be lower than the WAC, yes."

Responding further, Purepac cannot reasonably dispute the testimony of Mr. Cunningham who testified in his capacity as the vice president of sales and marketing at Purepac during the

time period of 2000 to 2002. *See* Deposition of Bradford Cunningham dated 10/23/2007 (“Cunningham Dep. 10/23/07”) (Reply Exhibit C attached hereto) at 23:6-24:5.

The testimony cited speaks for itself as follows:

“Q: And the usual – the relationship between prices would be AWP would be higher than WAC, and WAC would typically be higher than contract prices.

A: Typically, yes, that could be the way it goes.

Q: Well, not just could be. It was, wasn’t it?

A: I can’t say in every instance it was, but I can’t recall a specific example where it wasn’t.”

Cunningham Dep. 10/23/07 (Exhibit D to Purepac 56.1 Statement [Dkt. No. 6068, Sub-dkt. No. 69]) at 195:21-196:9.

**20. Purepac reduced the WACs in order to minimize accruals for chargebacks and to minimize prompt pay discounts. *See* Purepac 30(b)(6)(O’Malley) 9/19/07 Dep. (Exhibit E) at 104:7-107:5.**

**PUREPAC’S RESPONSE:** Disputed to the extent that it is unduly vague in terms of the time period to which it allegedly pertains. However, Purepac does not dispute that it, at undefined times, might have reduced WAC “when the difference between the contract price and the WAC price became Greater . . . and the accruals greater.”

**Plaintiffs’ Reply to Statement # 20:** Purepac disputes the Statement to the extent it is unduly vague in terms of the time period to which it pertains. Ms. O’Malley’s testimony in *Massachusetts v. Mylan, et al.* (C.A. No. 03-11865) covered the majority of the time period at-issue (1997 to 2003). *See* Purepac 30(b)(6)(O’Malley) 9/19/07 Dep. (Reply Exhibit D attached hereto) at 37:3-8. The parties agree that at certain times, Purepac may have reduced WACs in order to minimize accruals for chargebacks and prompt pay discounts.

**21. Purepac had three general categories of prices: AWP, WAC, and Contract prices. *See* Purepac 30(b)(6)(O’Malley) 9/19/07 Dep. (Exhibit E) at 128:9-14. These prices changed independently of each other. *See* Purepac 30(b)(6)(O’Malley) 9/19/07 Dep. (Exhibit E) at 128:19-129:7; 145:18-147:11.**

**PUREPAC'S RESPONSE:** Disputed to the extent the statement suggests that Purepac had only three prices.

**Plaintiffs' Reply to Statement # 21:** Purepac disputes the Statement only to the extent it suggests that Purepac had only three prices. The Statement does not suggest that Purepac had only three prices. The Statement is that Purepac had three general categories of prices: AWP, WAC and Contract Prices. This means that Purepac does not dispute the Statement. No further reply is required.

**22. Purepac invoiced wholesalers at WAC, but its WACs and AWP were independent of its contract prices. *Mylan*, 2008 WL 5650859 at \* 10.**

**PUREPAC'S RESPONSE:** Disputed. Purepac admits that at certain times WAC and AWP moved independent of its contract prices. However, 8 percent of Purepac's sales to wholesalers was at WAC. See paragraph 29, *infra*.

**Plaintiffs' Reply to Statement # 22:** Purepac's Response, "[h]owever, 8 percent of Purepac's sales to wholesalers was [sic] at WAC," does not address the Statement. The response is however an admission that 92% of Purepac's sales to wholesalers were not at WAC. Otherwise, the parties agree that Purepac's WAC and AWP were independent of its contract prices.

**23. Purepac knew that its published WACs were false. *Mylan*, 2008 WL 5650859 at \* 26.**

**PUREPAC'S RESPONSE:** Disputed. The citation does not support the proposition for which it stands. In fact, the Court did not decide knowledge or falsity of Purepac's WACs but acknowledged that defendants, including Purepac, used WAC as invoice price. *Mylan*, 2008 WL 5650589 at 25; see *Purepac 30(b)(6)(O'Malley)* 6/20/08 Dep. at 61:20-62:7; *Purepac 30(b)(6)(O'Malley)* 9/19/07 Dep. at 259:15-260:5. Purepac also disputes that *Mylan* has any legal effect in this case, as it involved different issues and is a nonfinal decision denying the parties' motions for summary judgment. See *Gonzalez v. Rodriguez*, 407 F.3d 425 (1st Cir. 2005) (collateral estoppel requires, among other conditions, identity of issues, and finality of the judgment).

**Plaintiffs' Reply to Statement # 23:** Purepac disputes the Statement to the extent it is not supported by the citation. The Court in *Mylan* applied the plain meaning rule and found that it was "clear that WAC [meant] 'the actual cost at which wholesalers acquired a drug.'" *Mylan*, 608 F.Supp.2d at 144. Purepac admits that only 8 percent of its sales to wholesalers were at WAC. *See* Purepac Response to Statement # 22. The Court found that "defendants' WACs were false for those drugs where WACs were not true prices paid by most wholesalers." *Mylan*, 608 F.Supp.2d at 144. Purepac admits that 92% of its sales to wholesalers were not at WAC. *See* Statement # 30 and Statement # 27 (92 percent of Purepac's sales to wholesalers were subject to chargebacks, which were not accounted for in Purepac's reported WACs). Therefore, Purepac cannot reasonably dispute that it knew its published prices were false.

**24. Purepac's WAC was grossly out of whack with the prices that were actually paid. *Mylan*, 2008 WL 5650859 at \* 26.**

**PUREPAC'S RESPONSE:** Disputed. Purepac disputes paragraph 24 because the citation refers to a general discussion in a court opinion not a finding of fact as to Purepac. Purepac further disputes that *Mylan* has any legal effect in this case, as it involved different issues and is a nonfinal decision denying the parties' motions for summary judgment. *See Gonzalez v. Rodriguez*, 407 F.3d 425 (1st Cir. 2005) (collateral estoppel requires, among other conditions, identity of issues, and finality of the judgment). Moreover, Purepac notes that approximately 8% of its sales to wholesalers were at WAC. *See* Purepac 30(b)(6)(O'Malley) 9/19/07 Dep. at 197:1-199:22; *see also* paragraphs 28, 29, *infra*.

**Plaintiffs' Reply to Statement # 24:** Purepac disputes the Statement to the extent the citation refers to a general discussion in a court opinion. And Purepac adds that approximately 8% of its sales to wholesalers were at WAC. Therefore, Purepac does not dispute that 92% of its sales were not at WAC.

**25. Purepac had a contract with Cardinal that provided Purepac pay Cardinal rebates that included baseline rebates. *See* O'Malley (6/20/08) 30(b)(6) Dep. (Exhibit B) at 175:11-181:15. Purepac had a profit share agreement with Cardinal for clonazepam. *See* Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B) at 201:14-203:2.**



**PUREPAC'S RESPONSE:** Purepac disputes that the existence of the cited contracts with Cardinal are material to the Plaintiffs' motion for partial summary judgment. *See* Local Rule 56.1 (requiring movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried"); *St. Paul Fire and Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005) (refusing to consider a summary judgment movant's immaterial facts). Purepac does not otherwise dispute the facts set forth in paragraph 25.

**Plaintiffs' Reply to Statement # 25:** The parties agree that Purepac had a contract with Cardinal that provided Purepac pay Cardinal rebates that included baseline rebates. The parties agree that Purepac had a profit share agreement with Cardinal for Lorazepam. Responding further, the statement is material because Purepac's payment of baseline (i.e. across-the-board) rebates on all products to one of the nation's three largest wholesalers confirms that it was standard practice for Purepac to sell at below WAC prices.

**26. Amerisource Bergen (f/k/a Bergen Brunswig) would receive a chargeback for sales made to Purepac's indirect customers who received a lower price than the WAC paid by Amerisource Bergen. *See* O'Malley (6/20/08) 30(b)(6) Dep. (Exhibit B) at 187:17-189:8.**

**PUREPAC'S RESPONSE:** Purepac objects to the statement in paragraph 26 to the extent it is unduly vague because it does not define a time period to which the statement refers.

Purepac disputes that Amerisource Bergen's receipt of chargebacks for sales to Purepac's indirect customers is material to the Plaintiffs' motion for partial summary judgment. *See* Local Rule 56.1 (requiring movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried"); *St. Paul Fire and Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005) (refusing to consider a summary judgment movant's immaterial facts). Purepac does not otherwise dispute the statements in paragraph 26.

**Plaintiffs' Reply to Statement # 26:** Ms. O'Malley testified regarding the entire time period at-issue (1997 to 2005). *See* Purepac 30(b)(6) (O'Malley) 6/20/08 Dep. (Reply Exhibit A attached hereto) at 32:9-12. Otherwise, Purepac disputes the statement only to the extent it is immaterial. Therefore, Purepac does not dispute the Statement. Purepac's payment of chargebacks to wholesalers is among the explanations for why Purepac's actual sales prices were

below WAC and why Purepac's WACs were false. Responding further, the 30(b)(6) testimony speaks for itself as follows:

“Q: In the case of the Clonazepam and the – in the case of the Clonazepam, even though Bergen may purchase at the WAC price initially, if Clonazepam was delivered to a customer through the GOP, the customer would be paying the contract price for Clonazepam; isn't that correct?

A: The indirect customer would pay the contract price from Bergen Brunswick. Bergen Brunswick would be invoiced at and pay the WAC price to Purepac.

Q: And then would receive a chargeback based on the difference between the contract price and the WAC; correct?

A: It is my understanding at some point in time, they would – Bergen would theoretically receive a chargeback for Clonazepam.

Q: Now, why do you say theoretically?

A: Well, I believe that we discussed a little bit earlier there were some percentages of wholesale sales that there wasn't a chargeback for.

Q: Fair enough. We absolutely did. However, here, if we are talking about the delivery of – if the – my understanding is that a wholesaler – let's use the Clonazepam example. If Bergen purchased – purchases Clonazepam at WAC from Purepac and then sells the Clonazepam product to a GOP member, to someone who is participating in your generic options program, then that member is only paying Bergen Brunswick the contract price for Clonazepam. So that transaction would trigger a chargeback payable to Bergen to make them whole for the below WAC source program.

A: I believe your understanding is correct.”

O'Malley (6/20/08) 30(b)(6) Dep. (Exhibit B to Purepac 56.1 Statement [Dkt. No. 6068, Sub-dkt. No. 69]) at 187:17-189:8. No further reply is required.

**27. The WAC reported or caused to be reported by Purepac does not account for these chargebacks, rebates and discounts. See Miranda Dep. 10/19/07(Exhibit C) at 138:21-140:18.**

**PUREPAC'S RESPONSE:** Purepac objects to the statement of paragraph 27 to the extent it is unduly vague as to the time period to which it pertains. Purepac does not dispute that its reported WACs did not account for chargebacks, rebates and discounts; Purepac considered WAC a list price. Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. at 61:20-62:7; Purepac 30(b)(6) (O'Malley) 9/19/07 Dep. at 259:15-260:5.

**Plaintiffs' Reply to Statement # 27:** The parties agree that Purepac's reported WACs did not account for chargebacks, rebates and discounts. Purepac objects to the Statement to the

extent it is vague as to the time period to which it pertains. Purepac's objection is futile. Purepac's Corporate designee testified that Purepac's reported WAC does not account for chargebacks, rebates and discounts. *See* Purepac 30(b)(6) (O'Malley) 6/20/08 Dep. (Exh. B to Purepac 56.1 Statement [Dkt. No. 6068, Sub-dkt. No. 69] ) at 99:15-100:6. Her testimony covered the time period at-issue (1997 to 2005). *See* Purepac 30(b)(6) (O'Malley) 6/20/08 Dep. (Reply Exh. A attached hereto) at 32:9-13. Ms. O'Malley's testimony follows:

“Q: My understanding is that the WACs that Purepac reported to the pricing compendia did not take into account the chargebacks paid to the wholesalers; is that correct?

A: That is my understanding. That would be correct, yes.

Q: Nor did the WAC take into account any billbacks paid to the wholesaler; is that right?

A: That would be my understanding also, yes.

Q: And the WACs also did not take into account any other rebates or payments that Purepac may have made to a wholesaler.

A: That is my understanding; correct.”

Purepac 30(b)(6) (O'Malley) 6/20/08 Dep. (Exh. B Purepac 56.1 Statement [Dkt. No. 6068, Sub-dkt. No. 69]) at 99:15-100:6.

**28. Purepac paid the wholesaler a chargeback to make up for the difference between the contract price paid by the indirect customer and the WAC price invoiced to the wholesaler. *See* O'Malley (6/20/08) 30(b)(6) Dep. (Exhibit B) at 187:17-189:8.**

**PUREPAC'S RESPONSE:** Purepac objects to the statement of paragraph 28 to the extent it is unduly vague as to the time period to which it pertains. Purepac further disputes the statement of paragraph 28 to the extent it suggests that Purepac paid all wholesalers chargebacks for all their sales. *See* paragraph 29, *infra*.

**Plaintiffs' Reply to Statement # 28:** Purepac disputes the Statement to the extent it is “vague as to the time period to which it pertains.” Ms. O'Malley's testimony concerned the entire time period at-issue (1997 to 2005). *See* Purepac 30(b)(6) (O'Malley) 6/20/08 Dep. (Reply Exhibit A attached hereto) at 32:9-12. Otherwise, Purepac disputes the Statement only to the extent it suggests Purepac paid all wholesalers chargebacks for all their sales. However, Purepac admits in response to Statement 29 below, that 92 percent of Purepac's sales to

wholesalers were subject to chargebacks at certain times. *See* Statement # 29. Responding further, Purepac's data reveals how frequently and persistently Purepac paid chargebacks to wholesalers throughout the time period at-issue: 1997 to 2005. *See* Exhibits #11.01 to 11.21 to Exhibit A to the Declaration of Harris L. Devor in Support of Plaintiffs' Motion for Partial Summary Judgment on Issues Relating to the Federal Upper Limit and Under New York Social Services Law § 145-b ("Devor Dec.") [Docket No. 6061, Sub-docket No. 61]. It supports the proposition that the payment of chargebacks occurred more than 90% of the time throughout the 1997-2005 period (in all but 9 of 203 cases in which Mr. Devor calculated an estimated WAC for Purepac, the published WAC was greater than the estimated WAC). *See* Exhibits 11.01, 11.04, 11.07, 11.10, 11.13, 11.16, 11.19 to Exhibit A to the Devor Dec. [Docket No. 6061, Sub-docket No. 61].

**29. Only 8 percent of sales to wholesalers were not subject to chargebacks; meaning only 8 percent of sales to wholesalers were at WAC. *See* Purepac 30(b)(6)(O'Malley) 9/19/07 Dep. (Exhibit E) at 197:1-199:22.**

**PUREPAC'S RESPONSE:** Purepac objects to the statement of paragraph 29 to the extent it is unduly vague as to the time period to which it pertains. Purepac does not dispute that at some time, 8 percent of its sales to wholesalers was not subject to chargebacks.

**Plaintiffs' Reply to Statement # 29:** Plaintiffs incorporate their reply to Statement #28 herein.

**30. Ninety-two percent of Purepac's sales to wholesalers were subject to chargeback. *See* Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B) at 90:14-94:13, 95:20-96:15.**

**PUREPAC'S RESPONSE:** Purepac objects to the statement of paragraph 30 to the extent it is unduly vague as to the time period it pertains. Purepac does not dispute that at some time, ninety-two percent of its sales to wholesalers was subject to chargeback.

**Plaintiffs' Reply to Statement # 30:** Ms. O'Malley's testimony pertained to the entire time period at-issue (1997 to 2005). *See* Purepac 30(b)(6) (O'Malley) 6/20/08 Dep. (Reply Exhibit A attached hereto) at 32:9-12. Furthermore, the data reveals how frequently and persistently Purepac paid chargebacks to wholesalers throughout the time period at-issue: 1997 to 2005. *See* Exhibits # 11.01 to 11.21 to Exhibit A to the Devor Dec. [Docket No. 6061, Subdocket No. 61]. At a minimum, the parties agree that, for some time at least, 92 percent of Purepac's sales to wholesalers were subject to chargebacks. No further reply is required.

**31. Purepac offered contract prices to its pharmacy customers.** *See* O'Malley, (6/20/08) 30(b)(6) Dep. (Exhibit B) at 85:21-86:1; 145:13-21 (Peyton); 88:9-18 (Walgreens); 146:20-147:11 (Caremark and Express Scripts). Some retail contracts provided product-specific pricing. *See* Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B) at 146:9-19. From 1997 to 2005, Purepac offered contract pricing for Clonazepam and Isosorbide Mononitrate to retail customers. *See* Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B) at 199:7-14; 206:2-11. In particular, Purepac entered into a profit share agreement with CVS for Isosorbide Mononitrate. *See* Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B) at 210:15-19. Purepac negotiates contract prices with its pharmacy customers that are typically below the published prices for each of its drugs. *See* Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B) at 90:1-13; 112:22-113:11, *see* Exhibit O'Malley 009 to Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit G).

**PUREPAC'S RESPONSE:** Purepac objects to the statements in paragraph 31 to the extent they are unduly vague as to the time period to which they pertain. Purepac further disputes the statements in paragraph 31 as immaterial to the extent that the cited testimony does not establish the purported facts for the relevant drugs. *See* Local Rule 56.1 (requiring movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried"); *St. Paul Fire and Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005) (refusing to consider a summary judgment movant's immaterial facts). Purepac disputes the phrases "pharmacy customers," "retail contracts," and "retail customers" because they are unduly vague and ambiguous. Purepac does not dispute that at a certain time it had a profit sharing agreement with CVS but disputes that this agreement is material to the Plaintiffs' motion for partial summary judgment. Plaintiffs' Exhibit G does not support the proposition for which it is cited.

**Plaintiffs' Reply to Statement # 31:** Ms. O'Malley testified regarding the entire time period at-issue (1997 to 2005). *See* Purepac 30(b)(6) (O'Malley) 6/20/08 Dep. (Reply Exhibit A attached hereto) at 32:9-12.

The testimony cited in statement #31 speaks for itself and reveals that plaintiffs have accurately described the pharmacy customers. The testimony is as follows:

“Q: Purepac had contracts and offered contract prices to certain retail chains; correct?

A: I believe that would be correct, yes.”

O'Malley, (6/20/08) 30(b)(6) Dep. (Exhibit B Purepac 56.1 Statement [Dkt. No. 6068, Sub-dkt. No. 69]) at 85:21-86:1;

“Q: Can you identify Peyton?

A: Peyton, to the best of my knowledge, is a retail warehousing chain also referred to as Kroger.

Q: Do you recall whether between '97 and '05 Purepac had a contractual relationship with Kroger or Peyton?

A: It is my understanding that, if not for all, part of the time there was a contract in place between Peyton and Purepac.”

*Id.* at 145:13-21;

“Q: Purepac had a contractual relationship with Walgreen; correct?

A: Yes. That's my understanding.

Q: Walgreen paid contract prices for the Purepac drugs?

A: That is my understanding, yes. Well, I'm sorry. If Walgreen, in fact, purchased those drugs, I am not a hundred percent sure if they did, but if they did, my understanding would be that they would be invoiced at a contract price.”

*Id.* at 88:9-18;

“Q: How about with regard to the contract between Purepac and entities such as Caremark or Express Scripts which are PBMs; correct?

A: Caremark and Express Scripts, is my understanding were mail-order.

Q: And between '97 and '05 are you aware whether Purepac had any contract in place with Caremark and/or Express Scripts?

A: I couldn't say with any degree of certainty, but there could have been contracts in place. Excuse me. By a contract you mean an actual contractual, signed Word document?

Q: That's correct.

A: I would believe that would be the case.”

*Id.* at 146:20-147:11.

The testimony cited speaks for itself and reveals that plaintiffs have accurately described the “retail contracts.” The testimony is as follows:

“Q: Can you – did you – Purepac’s retail contracts – withdrawn. Were Purepac’s contracts with retail chain product specific or were they more general?

A: General as in what sense?

Q: As in the sense that the contract provided terms that governed any purchase made by the retail pharmacy of any Purepac drug.

A: It is my understanding that the contract specific to the warehousing chains were product specific.”

*Id.* at 146:20-147:11.

The testimony cited speaks for itself and reveals that plaintiffs have accurately described the “retail customers.” The testimony is as follows:

“Q: Do you know, Ms. O’Malley, between the period of ’97 to ’05, do you know if Costco was the only retail customer with whom – to whom Purepac offered contract pricing for Clonazepam? A: I don’t believe Costco was the only customer that Purepac offered contract pricing to. It’s my understanding that Costco is not the only customer.”

*Id.* at 199:7-14;

“Q: And CVS was an indirect customer of Purepac; correct?

A: CVS, it’s my understanding that CVS had an indirect contract with Purepac through the wholesaler, yes.

Q: And – I’m sorry? CVS purchased Isosorbide Mononitrate and other products, but we are focusing on Isosorbide Mononitrate at the moment, at a contract price; correct?

A: That would be – appear to be correct, yes.”

*Id.* at 206:2-11.

Purepac disputes the statements in Paragraph 31 to the extent the cited testimony does not establish the purported facts for the relevant drugs. Therefore, Purepac does not dispute the third sentence: “From 1997 to 2005, Purepac offered contract pricing for Clonazepam and Isosorbide Mononitrate to retail customers.”



Purepac disputes that Purepac “had a profit sharing agreement with CVS” only to the extent it is immaterial. The Statement is material because it reveals that Purepac had additional incentives to create spread between reimbursement prices and actual prices. This bears on Purepac’s knowledge which is an issue on the motion. Thus, Purepac does not dispute the Statement.

Purepac does not dispute that it negotiates contract prices that are typically below the published prices for each of its drugs. No further reply is required.

**32. Purepac paid its pharmacy customers, such as Costco, rebates to encourage the purchase of Purepac products. See Purepac 30(b)(6)(O’Malley) 6/20/08 Dep. (Exhibit G) at 192:18-197:6; see also Exhibit O’Malley 018 to Purepac 30(b)(6)(O’Malley) 6/20/08 Dep. (Exhibit H). Such rebates were based on invoice purchases. See *Id.* Purepac paid rebates to the retail pharmacies, such as Target. Purepac 30(b)(6) (O’Malley) 6/20/08 Dep. (Exhibit B) at 210:22-213:20. The rebate reduced pharmacies’ contract prices even further below the WAC. See *Id.***

**PUREPAC’S RESPONSE:** Purepac objects to the statements in paragraph 32 to the extent they are unduly vague as to the time period to which they pertain. Purepac disputes the use of the terms “pharmacy customers” and “retail pharmacies.” Moreover, Purepac disputes the use of the phrase “even further” as vague and argumentative. Purepac does not dispute that rebates were part of the contract prices offered to some customers.

**Plaintiffs’ Reply to Statement # 32:** Ms. O’Malley testified regarding the entire time period at-issue (1997 to 2005). See Purepac 30(b)(6) (O’Malley) 6/20/08 Dep. (Reply Exhibit A attached hereto) at 32:9-12.

Purepac cannot reasonably dispute that the terms “pharmacy customers” or “retail pharmacies” are vague. The cited testimony makes clear that Purepac knows what these entities are. The testimony is as follows:

“Q: My question, Ms. O’Malley, and please take a moment to review the document, but this email suggests that Purepac paid a 27 percent rebate to the store Target in connection with Target’s purchases of Lorazepam. Would you agree with that?

A: Based on this copy of this, I guess, email from Dave Nielsen, it states that Target will receive a 27 percent rebate on this item which is Lorazepam in this memo.

Q: Do you recall whether Purepac offered product specific rebates for Lorazepam to other – withdrawn. Target was a retail customer of Purepac's; correct?

A: That would be my understanding.

Q: And do you recall whether Purepac offered rebates on Lorazepam to other retail customers?

A: I don't recall specifically.

Q: Do you have any reason to believe Target was the only retail customer who received rebates on Lorazepam? A: I have no reason to believe that either.

Purepac 30(b)(6) (O'Malley) 6/20/08 Dep. (Exhibit B Purepac 56.1 Statement [Dkt. No. 6068, Sub-dkt. No. 69]) at 211:12-213:20. The parties agree that rebates were part of the contract prices offered to some of Purepac's customers. Purepac does not dispute that the rebates reduced contract prices below the WAC.

**33. Some retail pharmacies were direct customers of Purepac. See O'Malley, Patricia (6/20/08) Dep. (Exhibit B) at 100:7-14. Direct customer contract prices tend to be lower than indirect customer contract prices. See Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B) at 100:15-101:10.**

**PUREPAC'S RESPONSE:** Purepac objects to the statement of paragraph 33 to the extent it is unduly vague as to the time period to which it pertains. Purepac disputes the use of the terms "retail pharmacies" because it is unduly vague. Purepac does not dispute that some retail chain warehouses were direct customers of Purepac. As stated, Purepac disputes the statement that "[d]irect customer contract prices tend to be lower than indirect customer contract prices" because it is overly broad and concerns the present. Purepac does not dispute that the prices for direct warehousing chains typically were lower than indirect contract prices.

**Plaintiffs' Reply to Statement # 33:** Ms. O'Malley testified regarding the entire time period at-issue (1997 to 2005). See Purepac 30(b)(6) (O'Malley) 6/20/08 Dep. (Reply Exhibit A attached hereto) at 32:9-12.

Purepac cannot reasonably dispute that it does not understand the term "retail pharmacies," or that the term is unduly vague. The testimony is as follows:

"Q: Turning now to the concept of direct sale, would you agree that a direct sale is a sale where Purepac sells its product directly to, for example, a retail chain pharmacy? And the product is delivered to the retail chain?

A: I consider the retail chain customer to be one of the direct customers of Purepac, that is correct.

Q: So the wholesaler, in a direct – where there is a direct contract – well, where Purepac has a contract with a customer who is going to obtain its product directly from Purepac, the contract price would tend to be lower than the indirect contract price; is that correct?

A: Can you just repeat that one more time?

Q: Do you know whether Purepac's direct customer contract prices are generally higher or lower than Purepac's indirect customer prices?

A: My understanding that typically – well, and we are just talking about direct warehousing chains; right?

Q: Yes, that's right.

A: It's my understanding that typically, they could be lower than the indirect contract prices. But not in all cases. I couldn't say for certain."

Purepac 30(b)(6)(O'Malley) 6/20/08 Dep. (Exhibit B Purepac 56.1 Statement [Dkt. No. 6068, Sub-dkt. No. 69]) at 100:7-101:10.

The parties agree that some retail chain warehouses were direct customers of Purepac. The parties agree that prices for direct warehousing chains typically were lower than indirect contract prices. No further reply is required.

**34. Purepac considered its contract prices to be confidential business information. See Purepac 30(b)(6)(O'Malley) 9/19/07 Dep. (Exhibit E) at 216:3-217:8.**

**PUREPAC'S RESPONSE:** Purepac disputes the statement in paragraph 34 to the extent that it implies that the confidentiality applied to reimbursement. Purepac does not dispute that its contract prices were confidential business information for purposes of its interactions with its customers, and as concerns its competitors

**Plaintiffs' Reply to Statement # 34:** The parties agree that Purepac's contract prices were confidential business information. No further reply is required.

### **Purepac Marketed the Spread**

**35. Purepac customers were interested in evaluating, and made purchasing decisions based on the reimbursement spread between its cost and the reimbursement price of an AWP. See Miranda Dep. 10/19/07 (Exhibit C) at 77:15-79:14 (Miranda would request authority for invoice pricing with a particular spread between the net price and the AWP based on a customer's request). See Exhibit Grauso 002 to the Deposition of James Grauso dated 10/19/07, ("Grauso Dep. Exhibit 002) (Exhibit I)<sup>1</sup>(email from James Grauso to Bob**

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<sup>1</sup> James Grauso worked for Purepac from 1997 to 2004. Deposition of James Grauso dated 10/19/07 ("Grauso Dep. 10/19/07") (Exhibit J) at 12:18-19. During that time, he held the following positions at

Jones recommending suggested AWP's that will maximize the customer's reimbursement spread); *see also* Exhibit Grauso Dep. Exhibit 003 (Exhibit K) (email string between Bob Miranda and Bob Jones approving of AWP change in response to customer request to increase AWP to match competitors' AWP spread).

**PUREPAC'S RESPONSE:** Purepac disputes the statements to the extent that it is overly broad and unduly vague. Moreover, whether Purepac customers were interested in evaluating, and made purchasing decisions based on the "reimbursement spread" is not material for Plaintiffs' motion for partial summary judgment. *See* Local Rule 56.1 (requiring movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried"); *St. Paul Fire and Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005) (refusing to consider a summary judgment movant's immaterial facts). Purepac further disputes that the parenthetical statement by Mr. Miranda supports Plaintiffs' statement. To the extent that Plaintiffs cite Mr. Grauso exhibits, testimony discussing these exhibits does not establish that Purepac knew that "customers were interested in evaluating and made purchasing decisions based on the reimbursement spread . . . ." *See* Deposition of James Grauso dated 10/19/07 at 102:6-110:20 (Exhibit PUR-1).

**Plaintiffs' Reply to Statement # 35:** Purepac disputes the Statement to the extent it is immaterial, to the extent it is not supported by the parenthetical statement, and to the extent the testimony referring to the exhibits cited does not support the statement. The testimony speaks for itself:

"Q: In connection with making any requests for authority to offer invoice pricing, have you ever made the request in the form of you'd like to have a certain spread between what the net price is and what the AWP price is?

A: I believe I may have.

Q: And what would be the circumstances in which you'd do that?

A: To the best of my recollection, I believe CareMark would be an example of a company who would be using such a term....

Q: I think you told me – and you correct me if I'm wrong – but I think you said that there were occasions when you would request invoice pricing from the people who exercised price authority at Purepac on the basis of having a certain spread between the net price and the AWP price. Is that right?

A: To the best of my recollection, it would be based on what recommendation a customer may have requested or the sales representative.

Q: And that would happen from time to time?

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Purepac: manager of marketing financial services, pricing manager, senior manager of sales analysis, and director of sales analysis. Grauso Dep. 10/19/07 (Exhibit J) at 13:16-14:18.

A: I believe so, yes.”

Miranda Dep. 10/19/07 (Exhibit C Purepac 56.1 Statement [Dkt. No. 6068, Sub-dkt. No. 69]) at 77:15-79:14.

In reponse to Statement # 35, Purepac cites the deposition of Mr. James Grauso, taken 10/19/07. Mr. Grauso’s testimony indicates he does not recall the email plaintiffs cite as Exhibit I to Statement #35. But Mr. Grauso’s email (Exhibit I) speaks for itself and reads as follows: “Bob, The attached spreadsheet contains my suggestions for AWP price increasees for Clonazepam. The new prices would help maximize the spread for customers while maintaining the generic status of Purepac’s product...”. *See* Exhibit I to Plaintiffs’ Local Rule 56.1 Statement of Undisputed Material Facts as to Purepac Pharmaceutical Co. [Docket No. 6068, Sub-docket No. 69].

Plaintiffs disagree that purchasing decisions based on reimbursement spread are immaterial. Purepac’s knowledge of and creation of spreads between reimbursement and actual prices are among the critical issues in this lawsuit and reveals Purepac’s knowledge that their reported prices were false.

### **Purepac’s AMPs**

**36. Purepac admits that drug manufacturers report AMPs to HHS. *See* Purepac Answer at ¶126. Purepac reports AMPs to CMS for each of its drugs. *Mylan*, 2008 WL 5650859 at \* 30.**

**PUREPAC’S RESPONSE: Purepac disputes that the statements in paragraph 36 are material to Plaintiffs’ motion for partial summary judgment, but does not dispute the statements set forth therein.**

**Plaintiffs’ Reply to Statement # 36: Purepac’s provision of AMPs is material because it reveals that Purepac can calculate and report actual prices to certain customers on a quarterly**

basis when it wants to do so. Similarly, Purepac could have calculated and reported accurate WACs. No further reply is required.

Dated: June 30, 2009

Respectfully submitted,

**City of New York and New York Counties in  
MDL 1456 except Nassau and Orange by**

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**CERTIFICATE OF SERVICE**

I, James P. Carroll Jr., hereby certify that I caused a true and correct copy of the foregoing PLAINTIFF'S REPLY LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS AS TO PUREPAC PHARMACEUTICAL CO., to be served on counsel of record via electronic service pursuant to paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File and Serve for posting and notification to all parties.

Dated: June 30, 2009

\_\_\_\_\_/s/\_\_\_\_\_  
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